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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,054	11/20/2003	Stephen N. Jones	07917-178001 / UMMC 03-14	3347

26161 7590 10/19/2005
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EXAMINER	
JOYCE, CATHERINE	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/719,054	JONES ET AL.	
	Examiner	Art Unit	
	Catherine M. Joyce	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-32 are pending.

2. It is noted that claims 7 and 8 improperly depend from claim 5. However, in the interests of compact prosecution, it will be assumed for restriction purposes that applicant made an inadvertent typographical error and that it was intended that claim 7 would properly depend from claim 4 appropriate correction is required.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, as drawn to a method of determining whether a subject has a hematopoietic cancer associated with a reduction of Wnt5a mRNA expression as disclosed in the specification, classified in class 435, subclass 4.

II. Claims 1-12, as drawn to a method of determining whether a subject has a hematopoietic cancer associated with a reduction of Wnt5a protein expression as disclosed in the specification, classified in class 435, subclass 4.

III. Claims 1-12, as drawn to a method of determining whether a subject has a hematopoietic cancer associated with a reduction of Wnt5a mRNA activity as disclosed in the specification, classified in class 435, subclass 4.

IV. Claims 1-12, as drawn to a method of determining whether a subject has a hematopoietic cancer associated with a reduction of Wnt5a protein activity as disclosed in the specification, classified in class 435, subclass 4.

V. Claims 1-12, as drawn to a method of determining whether a subject is at risk for a hematopoietic cancer associated with a reduction of Wnt5a mRNA expression as disclosed in the specification, classified in class 435, subclass 4.

VI. Claims 1-12, as drawn to a method of determining whether a subject is at risk for a hematopoietic cancer associated with a reduction of Wnt5a

protein expression as disclosed in the specification, classified in class 435, subclass 4.

VII. Claims 1-12, as drawn to a method of determining whether a subject is at risk for a hematopoietic cancer associated with a reduction of Wnt5a mRNA activity as disclosed in the specification, classified in class 435, subclass 4.

VIII. Claims 1-12, as drawn to a method of determining whether a subject is at risk for a hematopoietic cancer associated with a reduction of Wnt5a protein activity as disclosed in the specification, classified in class 435, subclass 4.

IX. Claims 13-22, as drawn to a method of identifying an anti-hematopoietic cancer agent comprising exposing a sample comprising a Wnt4a-expressing cell to a test agent and determining the level of Wnt5a gene expression as disclosed in the specification, classified in class 435, subclass 4.

X. Claims 13-22, as drawn to a method of identifying an anti-hematopoietic cancer agent comprising exposing a sample comprising a Wnt4a-expressing cell to a test agent and determining the level of Wnt5a gene activity as disclosed in the specification, classified in class 435, subclass 4.

XI. Claims 13-22, as drawn to a method of identifying an anti-hematopoietic cancer agent comprising exposing a sample comprising a Wnt4a-expressing cell to a test agent and determining the level of Wnt5a protein expression as disclosed in the specification, classified in class 435, subclass 4.

XII. Claims 13-22, as drawn to a method of identifying an anti-hematopoietic cancer agent comprising exposing a sample comprising a Wnt4a-expressing cell to a test agent and determining the level of Wnt5a protein activity as disclosed in the specification, classified in class 435, subclass 4.

XIII. Claims 23-29 and 32 as drawn to a method of treating a subject who has a Wnt5a-associated hematopoietic cancer, classified in class 514, subclass 44.

XIV. Claims 23-29 and 32 as drawn to a method of treating a subject who is at risk of developing a Wnt5a-associated hematopoietic cancer, classified in class 514, subclass 44.

3. The inventions are distinct, each from the other, because of the following reasons:

The inventions of groups I-XIV are materially distinct methods which differ at least in objectives, method steps and reagents. For example, Groups I-VIII are drawn to methods of determining whether a subject has or is at risk of developing a hematopoietic cancer, Groups IX-XII are drawn to a method of identifying an anti-hematopoietic cancer agent, and Groups XIII and XIV are drawn to methods of treating a subject who has or is at risk of having a Wnt5a associated cancer.

The inventions of Groups I-VIII are distinct from each other because they are directed to the measurement of differing cellular activities which would employ the use of functionally and structurally distinct reagents, i.e. measuring mRNA expression or measuring protein expression, or the diagnosis of different pathologic conditions, i.e. individuals having a hematopoietic cancer or individuals at risk of having a hematopoietic cancer. Groups IX-XII are distinct from each other because they are directed to the measurement of differing cellular activities which would employ the use of functionally and structurally distinct reagents, i.e. measuring mRNA expression or

measuring protein expression. Groups XIII and XIV are distinct from each other because they are directed to the treatment of different pathologic conditions, i.e. individuals having a hematopoietic cancer or individuals at risk of having a hematopoietic cancer

Searching the inventions of Groups I-XIV together would pose an undue search burden.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Groups I-VIII are further subject to the election of a single disclosed species.

Claim 4 is generic to a plurality of disclosed patentably distinct species comprising methods of determining whether a subject has, or is at risk of developing a hematopoietic cancer. The species are as follows: (a) acute myeloid leukemia (claims 4-6); (b) acute lymphoblast leukemia (claims 4-6); (c) an chronic leukemia (claims 4, 5); (d) Hodgkin's lymphoma (claims 4, 7); (e) B cell lymphoma (claims 4, 7, 8); (f) Burkitt's lymphoma (claims 4, 7, 8); (g) diffuse cell lymphoma (claims 4, 7, 8); (h) follicular lymphoma (claims 4, 7, 8); (i) immunoblastic large cell lymphoma (claims 4, 7, 8); (j) lymphoblastic lymphoma (claims 4, 7, 8); (k) mantle cell lymphoma (claims 4, 7, 8); (l) mycosis fungoides (claims 4, 7, 8); (m) post-transplantation lymphoproliferative disorder (claims 4, 7, 8); (n) small non-cleaved cell lymphoma (claims 4, 7, 8); (o) T-cell lymphoma (claims 4, 7, 8). The methods are patentably distinct because they are directed to diagnosis of different diseases with different pathologies and etiologies.

Claim 10 is generic to a plurality of disclosed patentably distinct species comprising methods of method of determining whether a subject has, or is at risk of developing a hematopoietic cancer. The species are as follows: (a) a B cell; (b) a T cell; (c) an eosinophil; (d) a basophil; (e) an erythrocyte; (f) a neutrophil; (g) a granulocyte;

(h) a monocyte (all claim 10). The methods are patentably distinct because they are directed to the use of different cell types.

6. Groups IX-XII are further subject to election of a single disclosed species.

Claim 15 is generic to a plurality of disclosed patentably distinct species comprising methods of identifying an anti-hematopoietic agent. The species are as follows: (a) a B cell; (b) a T cell; (c) an eosinophil; (d) a basophil; (e) an erythrocyte; (f) a neutrophil; (g) a granulocyte; (h) a monocyte (all claim 17). The methods are patentably distinct because they are directed to the use of different cell types.

Claim 13 is generic to a plurality of disclosed patentably distinct species comprising methods of identifying an anti-hematopoietic agent. The species are as follows: (a) a polypeptide; (b) a nucleic acid molecule; (c) a small non-peptide; (d) a non-oligonucleotide molecule; (e) a chemical entity. The methods are patentably distinct because they are directed to the use of structurally and functionally distinct reagents.

Claim 13 is generic to a plurality of disclosed patentably distinct species comprising methods of identifying an anti-hematopoietic agent. The species are as follows: (a) assessing the level of expression of cyclin D1; (b) assessing the extent of phosphorylation of protein kinase C; (c) assessing the extent of phosphorylation of calmodulin kinase II; (d) assessing the extent of phosphorylation of dishevelled; (e) assessing the extent of phosphorylation of LEF-1 (all claims 21 and 22). The methods are patentably distinct because they are directed to the assessment of structurally and functionally distinct cellular components.

7. Groups XIII and XIV are further subject to election of a single disclosed species.

Claim 27 is generic to a plurality of disclosed patentably distinct species comprising methods of method of determining whether a subject has, or is at risk of developing lymphoma. The species are as follows: (a) acute myeloid leukemia (claims

27-29); (b) acute lymphoblast leukemia (claims 27-29); (c) an chronic leukemia (claims 27 and 28); (d) Hodgkin's lymphoma (claims 27 and 30); (e) B cell lymphoma (claims 27, 30, and 31); (f) Burkitt's lymphoma (claims 27, 30, and 31); (g) diffuse cell lymphoma (claims 27, 30, and 31); (h) follicular lymphoma (claims 27, 30, and 31); (i) immunoblastic large cell lymphoma (claims 27, 30, and 31); (j) lymphoblastic lymphoma (claims 27, 30, and 31); (k) mantle cell lymphoma (claims 27, 30, and 31); (l) mycosis fungoides (claims 27, 30, and 31); (m) post-transplantation lymphoproliferative disorder (claims 27, 30, and 31); (n) small non-cleaved cell lymphoma (claims 27, 30, and 31); (o) T-cell lymphoma (claims 27, 30, and 31). The methods are patentably distinct because they are directed to the treatment of different diseases with different pathologies and etiologies.

Claim 23 is generic to a plurality of disclosed patentably distinct species comprising methods of method of determining whether a subject has, or is at risk of developing lymphoma. The species are as follows: (a) wherein the nucleic acid is administered to the subject systemically as contemplated in the specification (claims 23-31); (b) wherein the nucleic acid is administered to the subject by removing a cells from the subject and transducing the cell with a nucleic acid molecule and returning the cell to the subject (claim 32). The methods are patentably distinct because they are directed to highly divergent methods of nucleic acid molecule administration.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP. 809.02(a).

9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 of the other invention.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine M. Joyce
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER